



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0506]

William Kulakevich: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring William Kulakevich for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Kulakevich was convicted of one felony count under Federal law for conspiracy to commit offenses against the United States. The factual basis supporting Mr. Kulakevich's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Kulakevich was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of September 16, 2021 (30 days after receipt of the notice), Mr. Kulakevich had not responded. Mr. Kulakevich's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On July 23, 2019, Mr. Kulakevich was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Pennsylvania, when the court entered judgment against him for the offense of conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 2 and 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the indictment in Mr. Kulakevich's case, filed August 22, 2017, to which he plead guilty, from on or about April 2015, and continuing until May 2017, Mr. Kulakevich was the owner and a co-operator of a website, www.etizy.com, through which he sold and distributed a drug known as etizolam to consumers throughout the United States. Etizolam is a drug known as thienodiazepine, which is chemically similar to benzodiazepines and carries risks of dependency, toxicity, and the possibility of fatal overdose. Etizolam is not FDA-approved in the United States. Mr. Kulakevich and his co-conspirator illegally bought etizolam from an overseas supplier in India, after which he arranged to have it smuggled into the United States through the use of multiple post office boxes controlled by him and his coconspirator. To avoid Federal regulators, Mr. Kulakevich used false and misleading labeling and generally misrepresented the nature of the products sold on his website. Mr. Kulakevich reshipped the misbranded etizolam to customers located in the United States.

As a result of this conviction, FDA sent Mr. Kulakevich, by certified mail, on August 3, 2021, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Kulakevich's felony conviction under Federal law for conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 2 and 371, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported, relabeled, and then introduced unapproved etizolam products into interstate commerce. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Kulakevich's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Kulakevich of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kulakevich received the proposal and notice of opportunity for a hearing on August 17, 2021. Mr. Kulakevich failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. William Kulakevich has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Kulakevich is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Kulakevich is a prohibited act.

Any application by Mr. Kulakevich for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0506 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: December 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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